

**UNITED STATES DEPARTMENT OF COMMERCE****United States Patent and Trademark Office**

Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
-----------------	-------------	----------------------	---------------------

09/617,099 07/14/00 SEINO

S P19771

EXAMINER

HM12/1001

GREENBLUM & BERNSTEIN P L C  
1941 ROLAND CLARKE PLACE  
RESTON VA 20191

MITRA, R

ART UNIT	PAPER NUMBER
----------	--------------

1653

DATE MAILED:

10/01/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks****BEST AVAILABLE COPY**

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/617,099	SEINO ET AL.
	Examiner	Art Unit
	Rita Mitra	1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 26 July 2001.
- 2a) This action is FINAL.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-15 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) \_\_\_\_\_ is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claims 1-15 are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

15) <input type="checkbox"/> Notice of References Cited (PTO-892)	18) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____.
16) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	19) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
17) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.	20) <input type="checkbox"/> Other: _____.

### **DETAILED ACTION**

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1653.

#### *Election/Restriction*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1 and 2, drawn to a protein having the amino acid sequence set forth in SEQ ID NO: 1 and variants thereof; classified in Class 530, subclasses 350.
- II. Claims 3-12, drawn to a gene, DNA having nucleotide sequence set forth in SEQ ID NO: 2, encoding a protein having amino acid sequence of SEQ ID NO: 1, variants and fragments thereof, probe, primer, vector; classified in Class 536, subclass 23.5, 24.3, 24.32; Class 435, subclasses 69.1, 252.3, and 320.1.
- III. Claim 13, drawn to an antibody, directed to a protein set forth in SEQ ID NO: 1; classified in Class 530, subclass 387.1; Class 424, subclass 130.1.
- IV. Claim 14, drawn to a diagnostic agent for secretory disorders, comprising the probe of claim 9; classified in Class 536, subclass 23.1, 24.3, 24.32, Class 435, subclass 6.
- V. Claim 15, drawn to a diagnostic agent for secretory disorders, comprising the antibody of claim 13; classified in Class 530, subclass 387.1, Class 435, subclass 7.1

The inventions are distinct, each from the other because of the following reasons:

Groups I, II, and III are different products. Protein, DNA and antibody to the protein differ with respect to their structures and physicochemical properties, therefore each product is patentably distinct.

The protein of Group I is related to the antibody of group III by virtue of being the cognate antigen necessary for the production of antibody. Although the protein and antibody are related due to the necessary steric complimentarity of the two, they are distinct inventions because the protein can be used in another and materially different process from the use for production of the antibody, such as in a pharmaceutical composition in its own right, or to assay or purify the natural ligand of the protein if it is a receptor. Further, a protein and its cognate antibody are structurally and functionally distinct molecules with different amino acid compositions. Therefore, the inventions are distinct.

Groups I and IV, V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the Protein of group I is a separate and distinct chemical entity from agent of group IV and V. The protein has different functions from the agents of IV and V, and is not necessary for the practice of the claimed agents of IV and V. Therefore the inventions are distinct.

Groups II and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the

DNA of group II is a separate and distinct chemical entity from agent of group IV. The DNA has different functions from the agents of IV, and is not necessary for the practice of the claimed agents of IV. Therefore the inventions are distinct.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

Applicants are advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

### *Inquiries*

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rita Mitra whose telephone number is (703) 605-1211. The Examiner can normally be reached from 9:30 a.m. to 6:30 p.m. on weekdays. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Christopher Low, can be reached at (703) 308-2923. Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology

Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Fax Center number is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Rita Mitra, Ph.D.  
September 30, 2001

*Christopher S. F. Low*  
CHRISTOPHER S. F. LOW  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600